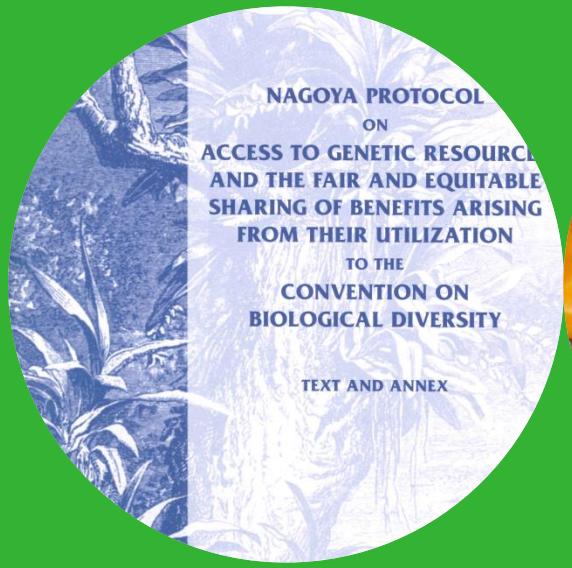
The Nagoya Protocol and the consequences for users of genetic resources

Martin Brink, CGN

28 August 2017



WAGENINGEN
UNIVERSITY & RESEARCH

Centre for Genetic Resources, the Netherlands

This presentation

1. The Nagoya Protocol
2. Implementation in the EU
3. Consequences for users of GR
4. Conclusions

This presentation

1. The Nagoya Protocol
2. Implementation in the EU
3. Consequences for users of GR
4. Conclusions

Access and Benefit-Sharing (ABS)

- Access and Benefit Sharing
  - regulation of access to genetic resources (GR) and associated information
  - sharing of benefits from the use of these GR between providers and users

- Possible benefits
  - monetary (e.g. royalties, funding for research)
  - non-monetary (e.g. scientific co-operation, technology transfer)

ABS example (South Africa)

- Product
  - extract of the 'kanna' plant (*Sceletium tortuosum*), used as basis for a commercial antidepressant (Zembrin)
- Partners
  - HG&H Pharmaceuticals
  - South African San Council (SASC)
  - 2 local communities
- Access
  - HG&H got permit from South Africa for bioprospecting and export of *S. tortuosum* for R&D and commercialization
- Benefit-sharing
  - SASC and local communities receive up-front payments (before commercialization) and royalties
  - employment creation for local communities through cultivation of kanna in South Africa

Convention on Biological Diversity

- Entry into force
  - 29 December 1993
- Objectives
  - conservation of biological diversity
  - sustainable use of its components
  - fair and equitable sharing of the benefits arising out of the utilization of genetic resources
- Membership
  - 196 parties

Convention on Biological Diversity

- Important elements
  - paradigm shift: genetic resources no longer 'heritage of mankind'; instead, states have sovereign rights over genetic resources
  - applies to all genetic resources (i.e. any material of plant, animal, microbial or other origin containing functional units of heredity, that is of actual or potential value), but not to human genetic resources
  - access shall be subject to Prior Informed Consent (PIC) of the Party providing such resources, unless otherwise determined by that Party
  - use and benefit-sharing must be agreed upon in Mutually Agreed Terms (MAT)

Convention on Biological Diversity

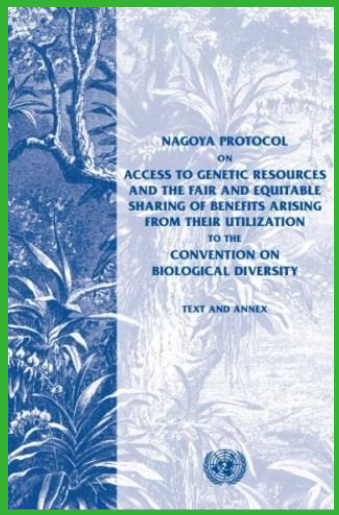
- Sovereign rights established by CBD (1993)

- National ABS legislations introduced: access restricted
  - Philippines (1995)
  - Costa Rica (1998)
  - Brazil (2001)
  - South Africa (2004)
  - Kenya (2006)

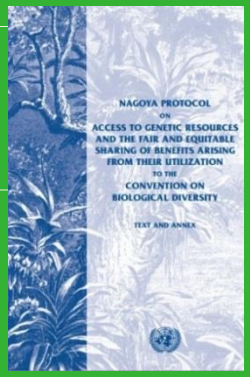
Convention on Biological Diversity

Nagoya Protocol

- Entry into force
  - 12 October 2014
- Protocol to the CBD
  - elaboration of the ABS provisions of the CBD
- Objective
  - the fair and equitable sharing of benefits arising from the utilisation of genetic resources (thereby contributing to the conservation of biological diversity and the sustainable use of its components)
- Membership
  - 99 parties (98 countries + EU)



Nagoya Protocol



- Important elements
  - compliance to ABS rules in provider countries to be monitored by countries where GR are used
  - each Party must provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation
  - each Party must designate Competent National Authorities (CNA), responsible for access, and National Focal Point (NFP), responsible for information supply
  - not only provisions on access to GR, but also on traditional knowledge associated with GR

This presentation

1. The Nagoya Protocol
2. Implementation in the EU
3. Consequences for users of GR
4. Conclusions

EU Regulation 511/2014

- Entry into force: 12 October 2014
- Applicable to GR and traditional knowledge associated with GR
  - accessed after entry into force of Nagoya Protocol for the EU (i.e. from 12 October 2014 onwards)
  - accessed from countries which have ratified the Nagoya Protocol and established access measures
- Utilisation of GR: to conduct research and development on the genetic and/or biochemical composition of GR
- Only deals with compliance, does NOT regulate access in EU countries

EU Regulation 511/2014

Obligations of users in EU

- to exercise 'due diligence' to ascertain that GR (and traditional knowledge associated with GR) they utilise have been accessed in accordance with ABS legislation of provider countries, and that benefits are shared
- To transfer and utilise GR (and associated TK) according to the MAT (Mutually Agreed Terms), if required
- Therefore:
    - seek, keep, and transfer relevant information to subsequent users
    - keep information for 20 years after end utilisation
- if GR is obtained from 'registered collection': 'due diligence' obligation considered fulfilled

EU Regulation 511/2014

Obligations of EU Member States

- request users to submit 'due diligence declaration'
  - when public or private funding is received for research project using GR
  - at the stage of final development of a product, e.g. when market approval/authorisation is sought
- carry out checks to monitor compliance
- lay down rules on penalties in case of non-compliance ('effective, proportionate and dissuasive')

Implementing Regulation (EU) 2015/1866

- Entry into force: 9 November 2015
- Lays down detailed rules on the implementation of Articles 5, 7 and 8 of the EU ABS Regulation
  - register of collections
  - due diligence declarations
  - best practices
- Annexes:
  - information to be provided
  - templates

EU Guidance Document

Mainly focusing on scope of EU ABS Regulation

- Temporal scope
  - applicable to GR accessed from 12 Oct 2014 onwards
- Geographic scope
  - applicable to GR from countries which have ratified the Nagoya Protocol and established access measures
  - applicable to utilisation within EU territory
- Personal scope
  - applicable to all users of GR resources
- Material scope
  - applicable to the utilisation of genetic resources and of traditional knowledge associated with GR
  - utilisation (R&D) includes basic research, applied research and product development

EU Guidance Document

- Out of material scope (no 'utilisation')
  - mere planting and harvesting
  - maintenance and management of a collection for conservation purposes, including storage, quality checks and verification
  - handling and storing of biological material and describing its phenotype
  - trade and exchange of GR as commodities
  - GR as testing/reference tools
  - use of biotechnology where GR are no object of R&D (e.g. use of yeasts in brewing beer)

EU Guidance Document

- In material scope ('utilisation')
  - description of a GR combined with research on that resource, i.e. to discover specific genetic and/or biochemical properties
  - 'litmus test': if your activity with GR creates new insight into characteristics of the GR which is of (potential) benefit to the further process of product development, it is 'utilisation'
  - breeding to create new varieties
  - genetic modification
  - creation and improvement of GR used in biotechnology (e.g. of yeasts to be used in brewing process)

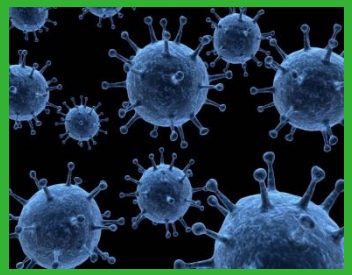
EU Guidance Document

- Unresolved issues
  - ➢ mainly: what is utilisation? (material scope)

- Further sector-specific guidance documents under development in 2016/2017

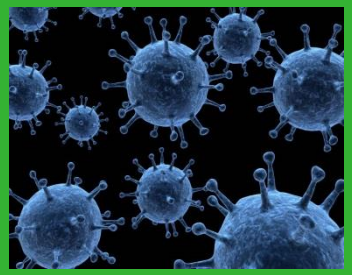
EU Sectorial Guidance Documents

- Initial sectors (start 2016, finish 2017)
  1. animal breeding sector
  2. plant breeding sector
  3. biocontrol/biostimulants sector
  4. cosmetics sector
  5. pharmaceutical sector
  6. food and beverage industry sector
  7. biotechnology industry sector
- Additional domains (start 2017)
  8. public research institutions
  9. collection holders



EU Sectorial Guidance Documents

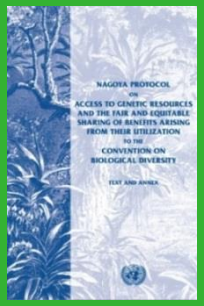
- Important issues currently discussed
  - where does identification/description stop and R&D start (e.g. genome sequencing)?
  - in case of mass screening: permits needed for every accession?
  - when does utilisation end ('cut-off point')?
  - what about the human biome?
  - are commercial plant varieties included?
  - are laboratory strains included?
  - derivatives: when do ABS rules apply?

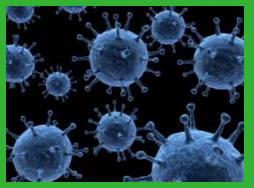


ABS landscape EU

- CBD (1993)
- Nagoya Protocol (2014)
- EU legislation (2014 -)

EU ABS Regulation
EU Implementing Regulation
EU Guidance Document EU
EU Sectorial Guidance Documents





This presentation

1. The Nagoya Protocol
2. Implementation in the EU
3. Consequences for users of GR
4. Conclusions

Basics

- Is provider country party to the Nagoya Protocol?
  - no ➡ national access legislation of provider country applicable; Nagoya Protocol not applicable
  - yes ➡ national access legislation of provider country applicable; Nagoya Protocol applicable

    ⬇

    Utilisation in EU?
    - yes ➡ EU ABS Regulation applicable
    - no ➡ other compliance rules may be applicable

What must users of GR do?

- If you perform R&D in the EU on genetic resources accessed from 12 October 2014 onwards:

1. check access rules of the provider country
   - ABS Clearing House (https://absch.cbd.int/)
   - National Focal Point (NFP) of the provider country
2. where required, seek permission from the Competent National Authority (CNA) of the provider country (PIC: 'Prior Informed Consent')
3. negotiate conditions with provider, and lay these down in a contract (MAT: 'Mutually Agreed Terms')

What must users of GR do?

4. use the GR only in accordance with the conditions agreed with the provider country
5. carefully document the use
6. keep all documentation for 20 years
7. make 'due diligence declaration' in case of submitting proposals for grants and of marketing products
8. pass on obligations to further users

What must users of GR document?

- 'internationally-recognised certificate of compliance'
  - = document posted by the provider country on the ABS Clearing House website (http://www.cbd.int/abs/)

or:

- document(s) showing:
  - date and place of access of resources or traditional knowledge
  - description of the genetic resources or of traditional knowledge
  - source from which the genetic resources or traditional knowledge associated with genetic resources were obtained, as well as subsequent users (development chain)
  - rights and obligations relating to access and benefit-sharing including for subsequent applications and commercialisation
  - access permits, where applicable (from CNA)
  - MAT, including benefit-sharing arrangements, where applicable

What more can users of GR do?

- Document what you had already in possession before 12 October 2014
  - not a legal obligation but a precaution to avoid future conflicts
- Be prepared for questions on the legal status of acquired genetic resources
  - e.g. publication policies journals
- Consider your options in accessing genetic resources
  - worth the effort?
  - from a collection, or from nature or farmers' fields?
  - from which country (track record)?

This presentation

1. The Nagoya Protocol
2. Implementation in the EU
3. Consequences for users
4. Conclusions

Conclusions

1. Since 29 December 1993: CBD in force
   - national sovereignty over genetic resources
   - countries may regulate access to GR in national legislation

2. Since 12 October 2014: Nagoya Protocol in force
   - compliance to national access legislation of provider countries to be monitored to be monitored by countries where GR are used

3. Since 12 October 2014: EU ABS Regulation in force
   - EU users must exercise 'due diligence' to make sure GR are accessed in accordance with national legislation of provider countries
   - compliance monitored by EU countries
   - access not regulated at EU level

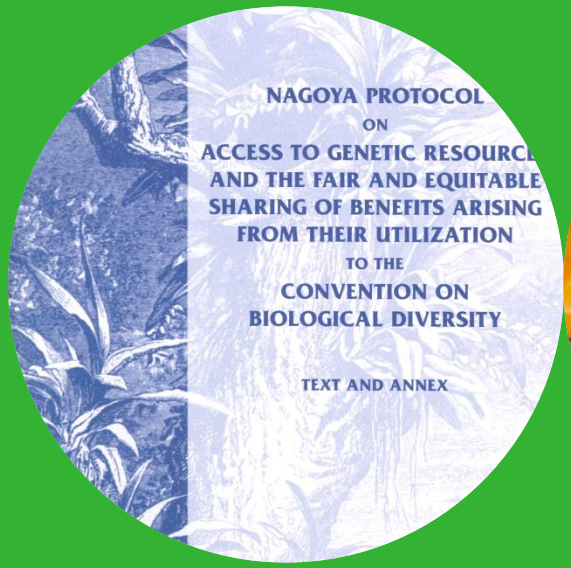
Conclusions

4. Geographical, temporal and personal scope of EU ABS Regulation clear, but material scope ('what is utilisation') still under discussion
5. Seeking, keeping and transferring information on access conditions and benefit-sharing agreements has become essential
6. What must users of GR do?
    - document what you have in stock
    - secure legal status of new materials
    - document how you use new materials for R&D
    - make 'due diligence declarations'
    - pass on obligations to further users

Thank you!

More information:

- www.absfocalpoint.nl
- martin.brink@wur.nl



WAGENINGEN
UNIVERSITY & RESEARCH

Centre for Genetic Resources, the Netherlands